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10/809,217	03/25/2004	Shoji Miyazaki	55220/844	6571
7590 05/06/2009 Alan D. Miller			EXAMINER	
Amster, Rothstein Ebenstein LLP			NOGUEROLA, ALEXANDER STEPHAN	
90 Park Avenu New York, NY			ART UNIT	PAPER NUMBER
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			MAIL DATE	DELIVERY MODE

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/809 217 MIYAZAKI ET AL. Office Action Summary Examiner Art Unit ALEX NOGUEROLA 1795 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 03 February 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 45-65 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 45-65 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 09/889,243. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
5) Information Disclosure Glotement(s) (PTO-95ins)
Paper Nos(SMall Date 2022209)
6) Other: 105 of 107422009
6) Other: 105 of 107422009

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DETAILED ACTION

Response to Amendment

 Applicant's amendment of February 02, 2009 does not render the application allowable. As discussed and shown in the rejections bleow, contrary to Applicant's assertion, the second slits in Wlnarta partly surround the reagent layer.

Status of the Rejections pending since the Office action of October 17, 2008

2. All of the double patenting rejections are <u>maintained</u>. Although Applicant has submitted terminal disclaimers the PTO paralegal assigned to process them was unable to do so because <u>the signing attorney is not of record in the file</u>. The new limitations are still met by the double patenting rejections as originally presented. In particular, claim 10 of US 6,875,327 B1 "the reagent layer being provided on the electrode part in the specimen supply path" (claim 1, from which claim 10 depends) and "wherein the

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reagent layer of the biosensor is formed by dripping a reagent, and the biosensor

provides a second type of slits around a position where the reagent is dripped."

Claim 47 of copending application 10/809,240 also, similarly, meets the new limitations

of claims 45.

3. All of the prior art rejections have been withdrawn, but only to be written in light of

the amendment to claim 45, otherwise they are the same as before.

Claim Rejections - 35 USC § 102

 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

 Claims 45, 53-55, and 62-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Winarta et al. US 6,287,451 B1 ("Winarta").

Addressing claim 45, Winarta discloses biosensor for quantifying a substrate included in a sample liquid (col. 01:01-20) comprising:

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(Figure 2),

a first insulating support (20) and a second insulating support (50);

an electrode part comprising at least a working electrode and a counter

electrode (col. 10:36-40 – note that since there is not a separate counter electrode one with ordinary skill in the art would understand that the reference electrode also functions as a counter electrode);

a specimen supply path (112) for introducing the sample liquid to the electrode

part (col. 10:63 - col. 11:02); and

a reagent layer employed for quantifying the substrate included in the sample

liquid (col. 10:41-53 and col. 09:14-26),

where the electrode part, the specimen supply path, and the reagent layer are situated between the first insulating support and the second insulating support

the specimen supply path being provided on the electrode part, and the reagent layer being provided on the electrode part in the specimen supply path, respectively (Figure 2 and col. 10:41-43),

the electrode part being dividedly formed by a first type of slits provided on an electrical conductive layer which is formed on the whole or part of an internal surface of one or both of the first insulating support and the second insulating support (Figure 2 and col. 07:58-61).

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the reagent layer is positioned on the electrode part (col. 06:03-10 and col. 08:26-51, note especially the reagent in cutout W2) and formed by dripping a reagent (this is a product-by-process limitation that does not patentably distinguish the dispensed reagent of Winarta, which was probably "dripped", from Applicant's reagent), and

a second type of slits (the three angled segments of slit 28 at the front end of the biosensor shown in Figure 2 can be construed as three second type of slits as they are not for forming electrodes, but means to "avoid potential static problems which could give rise to a noisy signal" – col. 07:63 to col. 08:01) is provided around a position where the reagent is dripped on the electrodes so as to partly surround the dripped position (in Figure 2, reproduced below, consider the location of cutout W2 in relation to the second type of slits. Also consider the following simplified diagram).

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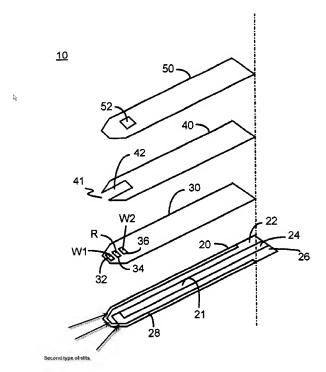
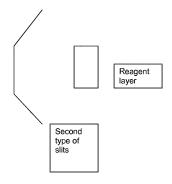


Fig. 2

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Addressing claim 53, for the additional limitations of this claim see Figure 2 in Winarta and note spacer 40.

Addressing claim 54, for the additional limitation of this claim see Figures 1 and 2; col. 11:09-11; and col. 11:39-41.

Addressing claim 55, for the additional limitation of this claim note element 52 in Figure 2.

Addressing claims 62-65, for the additional limitations of these claims see col. 07:44-51; col. 08:26-52; and col. 09:14-40.

 Claims 46, 47, 49, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winarta et al. US 6,287,451 B1 ("Winarta") in view of Ikeda et al. US 5,582,697 ("Ikeda").

Winarta discloses biosensor for quantifying a substrate included in a sample liquid (col. 01:01-20) comprising:

a first insulating support (20) and a second insulating support (50);

an electrode part comprising at least a working electrode and a counter

electrode (col. 10:36-40 – note that since there is not a separate counter electrode one with ordinary skill in the art would understand that the reference electrode also functions as a counter electrode):

a specimen supply path (112) for introducing the sample liquid to the electrode part (col. 10:63 – col. 11:02); and

a reagent layer employed for quantifying the substrate included in the sample liquid (col. 10:41-53 and col. 09:14-26),

where the electrode part, the specimen supply path, and the reagent layer are situated between the first insulating support and the second insulating support (Figure 2),

the specimen supply path being provided on the electrode part, and the reagent layer being provided on the electrode part in the specimen supply path, respectively (Figure 2 and col. 10:41-43),

the electrode part being dividedly formed by a first type of slits provided on an electrical conductive layer which is formed on the whole or part of an internal surface of one or both of the first insulating support and the second insulating support (Figure 2 and col. 07:58-61),

the reagent layer is positioned on the electrode part (col. 06:03-10 and col. 08:26-51, note especially the reagent in cutout W2) and formed by dripping a reagent (this is a product-by-process limitation that does not patentably distinguish the dispensed reagent of Winarta, which was probably "dripped", from Applicant's reagent), and

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a second type of slits (the three angled segments of slit 28 at the front end of the biosensor shown in Figure 2 can be construed as three second type of slits as they are not for forming electrodes, but means to "avoid potential static problems which could give rise to a noisy signal" – col. 07:63 to col. 08:01) is provided around a position where the reagent is dripped on the electrodes so as to partly surround the dripped position (in Figure 2, reproduced below, consider the location of cutout W2 in relation to the second type of slits. Also consider the following simplified diagram.).

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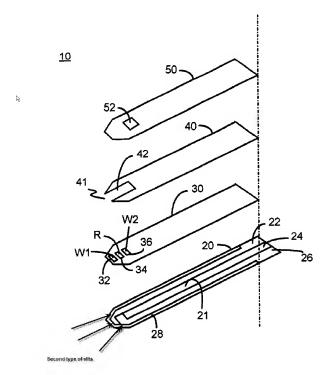
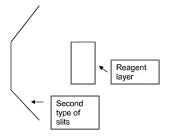


Fig. 2

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Addressing claim 46, Wlnarta only discloses linear slits. See Figure 2 in Wlnarta. However, to make the second type of slits arc-shaped is just a mere arbitrary change in shape, unless Applicant shows that the slit shape is significant. See MPEP 2144.04.IV.B.

Addressing claim 47, Winarta does not disclose the electrode part further comprising a detecting electrode; however, Winarta does disclose providing a third electrode, W2, that could also function as a detecting electrode. As shown by Ikeda a

third electrode located at the end of a capillary channel in a biosensor test strip could be used as a detecting electrode in addition to alternatively being involved in the actual sample measurement (abstract and Figure 1).

Addressing claim 49, for the additional limitations of this claim see Figure 2 and col. 07:58-61 in Winarta. Recall that Ikeda is only cited for showing that an electrode at the end of a capillary channel in a biosensor test strip could also be used as a detecting electrode.

Addressing claim 51, note that Winarta discloses that the cutouts for the working electrodes have the same area and that the cutout for the counter/reference electrode may be the same or larger than that for the each working electrode. See col. 04:48-54. Since electrode W2 is being construed as a detecting electrode (actually a dual purpose pseudo working electrode/ detecting electrodes) the sum of the area for electrode "R" (the counter/reference electrode) and the area of W2 (detecting /pseudo working electrode) will necessarily be greater than that of the W1 (the working electrode).

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as a counter electrode);

 Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over WInarta in view of Kawaguri et al. US 5.171.689 ("Kawaguri").

Winarta discloses biosensor for quantifying a substrate included in a sample liquid (col. 01:01-20) comprising:

a first insulating support (20) and a second insulating support (50);
an electrode part comprising at least a working electrode and a counter
electrode (col. 10:36-40 – note that since there is not a separate counter electrode one
with ordinary skill in the art would understand that the reference electrode also functions

a specimen supply path (112) for introducing the sample liquid to the electrode part (col. $10:63-col.\ 11:02$); and

a reagent layer employed for quantifying the substrate included in the sample liquid (col. 10:41-53 and col. 09:14-26),

where the electrode part, the specimen supply path, and the reagent layer are situated between the first insulating support and the second insulating support (Figure 2),

the specimen supply path being provided on the electrode part, and the reagent layer being provided on the electrode part in the specimen supply path, respectively (Figure 2 and col. 10:41-43).

the electrode part being dividedly formed by a first type of slits provided on an electrical conductive layer which is formed on the whole or part of an internal surface of one or both of the first insulating support and the second insulating support (Figure 2 and col. 07:58-61),

the reagent layer is positioned on the electrode part (col. 06:03-10 and col. 08:26-51, note especially the reagent in cutout W2) and formed by dripping a reagent (this is a product-by-process limitation that does not patentably distinguish the dispensed reagent of Winarta, which was probably "dripped", from Applicant's reagent), and

a second type of slits (the three angled segments of slit 28 at the front end of the biosensor shown in Figure 2 can be construed as three second type of slits as they are not for forming electrodes, but means to "avoid potential static problems which could give rise to a noisy signal" – col. 07:63 to col. 08:01) is provided around a position where the reagent is dripped on the electrodes so as to partly surround the dripped position (in Figure 2, reproduced below, consider the location of cutout W2 in relation to the second type of slits. Also consider the following simplified diagram.).

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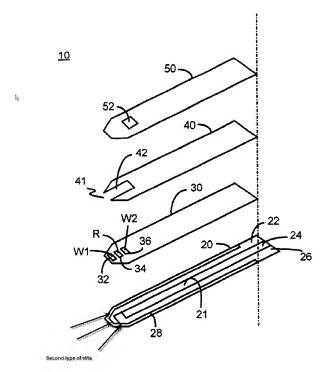
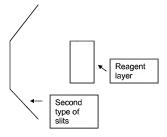


Fig. 2

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Winarta discloses that the cutouts exposing the working electrodes may the same or different than the size of the cutout exposing the reference electrode. See col. 04:50-53. Alternatively, although not needed to meet the claim, Kawaguri teaches that making the area of a counter/reference electrode larger than that of the working electrodes in a solid-state biosensor will stabilize the potential. See col. 04:06-21.

 Claims 56-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wlnarta in view of Kawanaka et al. US 6,599,406 B1 ("Kawanaka").

Addressing claim 56, Winarta discloses biosensor for quantifying a substrate included in a sample liquid (col. 01:01-20) comprising:

a first insulating support (20) and a second insulating support (50);
an electrode part comprising at least a working electrode and a counter
electrode (col. 10:36-40 – note that since there is not a separate counter electrode one
with ordinary skill in the art would understand that the reference electrode also functions
as a counter electrode);

a specimen supply path (112) for introducing the sample liquid to the electrode part (col. 10:63 – col. 11:02); and a reagent layer employed for quantifying the substrate included in the sample liquid (col. 10:41-53 and col. 09:14-26).

where the electrode part, the specimen supply path, and the reagent layer are situated between the first insulating support and the second insulating support (Figure 2),

the specimen supply path being provided on the electrode part, and the reagent layer being provided on the electrode part in the specimen supply path, respectively (Figure 2 and col. 10:41-43),

the electrode part being dividedly formed by a first type of slits provided on an electrical conductive layer which is formed on the whole or part of an internal surface of one or both of the first insulating support and the second insulating support (Figure 2 and col. 07:58-61),

the reagent layer is positioned on the electrode part (col. 06:03-10 and col. 08:26-51, note especially the reagent in cutout W2) and formed by dripping a reagent (this is a product-by-process limitation that does not patentably distinguish the dispensed reagent of Winarta, which was probably "dripped", from Applicant's reagent), and

a second type of slits (the three angled segments of slit 28 at the front end of the biosensor shown in Figure 2 can be construed as three second type of slits as they are not for forming electrodes, but means to "avoid potential static problems which could give rise to a noisy signal" – col. 07:63 to col. 08:01) is provided around a position where the reagent is dripped on the electrodes so as to partly surround the dripped position (in Figure 2, reproduced below, consider the location of cutout W2 in relation to the second type of slits. Also consider the following simplified diagram.).

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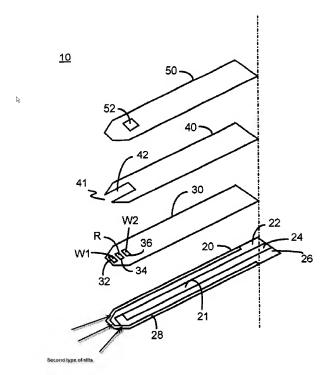
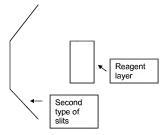


Fig. 2

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Winarta does not disclose providing a third type of slits for dividing the electrical conductive layer to define an area of the electrode part.

Kawanaka discloses a concentration measuring apparatus, test strip for the concentration measuring apparatus, biosensor system and method for forming terminal on the test strip. The test strip is substantially planar and comprises laminated layers and a type of slits for dividing the electrical conductive layer to define an area of the

electrode part. See the title, abstract, Figures 33, 34, 8, 9, 20, 22, 24, and 28-32. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a type of slits for dividing the electrical conductive layer to define an area of the electrode part as taught by Kawanaka in the invention of Wlnarta, which would be a third type of slits, because as taught by Kawanaka then the information regarding the test strip, such as the particular analyte the test strip is configured to measure and the appropriate potential to be used during the measurement, can be conveyed to the

Addressing claim 57, for the additional limitations of this claim see Figure 2 in Winarta and Figures 8, 9, 20, 22, 24, and 28-32 in Kawanaka.

measuring apparatus. See col. 02:45 - col. 05:07.

Addressing claims 58 and 59, Winarta discloses biosensor for quantifying a substrate included in a sample liquid (col. 01:01-20) comprising:

a first insulating support (20) and a second insulating support (50); an electrode part comprising at least a working electrode and a counter

electrode (col. 10:36-40 – note that since there is not a separate counter electrode one with ordinary skill in the art would understand that the reference electrode also functions as a counter electrode);

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a specimen supply path (112) for introducing the sample liquid to the electrode part (col. 10:63 – col. 11:02); and

a reagent layer employed for quantifying the substrate included in the sample liquid (col. 10:41-53 and col. 09:14-26),

where the electrode part, the specimen supply path, and the reagent layer are situated between the first insulating support and the second insulating support (Figure 2),

the specimen supply path being provided on the electrode part, and the reagent layer being provided on the electrode part in the specimen supply path, respectively (Figure 2 and col. 10:41-43),

the electrode part being dividedly formed by a first type of slits provided on an electrical conductive layer which is formed on the whole or part of an internal surface of one or both of the first insulating support and the second insulating support (Figure 2 and col. 07:58-61),

the reagent layer is formed by dripping a reagent (this is a product-by-process limitation that does not patentably distinguish the dispensed reagent of Winarta, which was probably "dripped", from Applicant's reagent), and

a second type of slits (the three angled segments of slit 28 at the front end of the biosensor shown in Figure 2 can be construed as three second type of slits as they are

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not for forming electrodes, but means to "avoid potential static problems which could give rise to a noisy signal" – col. 07:63 to col. 08:01) is provided around a position where the reagent is dripped (Figure 2).

Winarta does not disclose providing in the biosensor information of correction data generated for each production lot of the biosensor, which correspond to characteristics concerning output of an electrical change resulting from a reaction between the sample liquid and the reagent layer and can be discriminated by a measuring device employing the biosensor.

Kawanaka discloses a concentration measuring apparatus, test strip for the concentration measuring apparatus, biosensor system and method for forming terminal on the test strip. The test strip is substantially planar and comprises laminated layers and a type of slits for dividing the electrical conductive layer to define an area of the electrode part, which would be a fourth type of slits (the third type of slit conveys information on what analyte the biosensor is configured to detect - see rejection of claim 56 above). See the title, abstract, Figures 33, 34, 8, 9, 20, 22, 24, and 28-32. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a type of slits for dividing the electrical conductive layer to define an area of the electrode part as taught by Kawanaka in the invention of Winarta because as taught by Kawanaka then the information of correction data regarding the test strip as claimed (calibration data) can be conveyed to the measuring apparatus. See col. 05:44 – col. 06:08.

Addressing claim 60, Winarta discloses biosensor for quantifying a substrate included in a sample liquid (col. 01:01-20) comprising:

a first insulating support (20) and a second insulating support (50);
an electrode part comprising at least a working electrode and a counter
electrode (col. 10:36-40 – note that since there is not a separate counter electrode one
with ordinary skill in the art would understand that the reference electrode also functions
as a counter electrode);

a specimen supply path (112) for introducing the sample liquid to the electrode part (col. 10:63 – col. 11:02); and

a reagent layer employed for quantifying the substrate included in the sample liquid (col. 10:41-53 and col. 09:14-26),

where the electrode part, the specimen supply path, and the reagent layer are situated between the first insulating support and the second insulating support (Figure 2),

the specimen supply path being provided on the electrode part, and the reagent layer being provided on the electrode part in the specimen supply path, respectively (Figure 2 and col. 10:41-43),

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the electrode part being dividedly formed by a first type of slits provided on an electrical conductive layer which is formed on the whole or part of an internal surface of one or both of the first insulating support and the second insulating support (Figure 2 and col. 07:58-61),

the reagent layer is formed by dripping a reagent (this is a product-by-process limitation that does not patentably distinguish the dispensed reagent of Winarta, which was probably "dripped", from Applicant's reagent), and

a second type of slits (the three angled segments of slit 28 at the front end of the biosensor shown in Figure 2 can be construed as three second type of slits as they are not for forming electrodes, but means to "avoid potential static problems which could give rise to a noisy signal" – col. 07:63 to col. 08:01) is provided around a position where the reagent is dripped (Figure 2).

Winarta does not disclose providing a third type of slits and a fourth type of slits formed by processing the electrical conductive layer by a laser.

Kawanaka discloses a concentration measuring apparatus, test strip for the concentration measuring apparatus, biosensor system and method for forming terminal on the test strip. The test strip is substantially planar and comprises laminated layers and a type of slits for dividing the electrical conductive layer to define an area of the electrode part, which would be a third type of slits and a fourth type of slits (the third type of slit conveys information on what analyte the biosensor is configured to detect - see rejection of claim 56 above). See the title, abstract, Figures 33, 34, 8, 9, 20, 22, 24,

and 28-32. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a third type of slits for dividing the electrical conductive layer to define an area of the electrode part and a fourth type of slits as taught by Kawanaka in the invention of Wlnarta because as taught by Kawanaka then the information of correction data regarding the test strip as claimed can be conveyed to the measuring apparatus. For example, the third slits can indicate the particular analyte the test strip is configured to measure and the fourth slits can indicate calibration date. See col. 02:45 – col. 05:07 and col. 05:44 – col. 06:08.

As for the slits being formed using a laser, this is a product-by-process limitation that does not further patentably limit the slits. In any event Winarta discloses forming slits in the electrically conductive material using a laser. See col. 04:15-30 and col. 07:54-63.

Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winarta
in view of Kawanaka as applied to claims 56-60 above, and further in view of Fujiwara
et al. US 6,004,441 ("Fujiwara").

Winarta as modified by Kawanaka does not appear to mention the possible widths of the silts; however, as noted in the rejection of claim 60 Winarata does disclose using a laser to form the slits.

Fujiwara discloses making slits in a metal film to make electrodes or a test strip type biosensor. The slits are made using a laser and be 70 microns (=0.07mm) in width. See the abstract and col. 02:52-59. In light of Fujiwara Applicant's claimed slit width range of 0.005 mm to 0.3 mm is just a matter of scaling the biosensor to the expected volume range of sample, by , for example, making smaller more closely spaced electrodes for smaller expected sample volumes.

Final Rejection

10. Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later $% \left(1\right) =\left(1\right) \left(1\right) \left($

than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-

1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Noguerola/ Primary Examiner, Art Unit 1795

May 1, 2009